

REMARKS

Amendments

Claim 1 is amended clarify the claim language and limit the claim to a polypeptide gene product. Support for the amendments can be found at page 36, lines 3-11, and in Claim 5.

Claim 14 is amended to limit the probe to a polypeptide probe.

No new matter is added. The Examiner is requested to enter the amendment.

Applicants reserve the rights to file one or more continuation applications directed to the non-elected claim scope.

Restriction Requirement

In response to the restriction requirement, Applicants are electing Group I, Claims 1-21, which are drawn to a method for discriminating metaplasias from neoplastic lesions in a biological sample in the course of cytological testing procedures, wherein the INK4a gene products are polypeptides.

Species Election Requirement

In response to the species election requirement, Applicants respectfully bring to the Examiner's attention to page 36, lines 3-11, where the claimed invention is clearly defined:

The discrimination according to the present invention is based on the presence or absence of cells expressing p14ARF and on the presence or absence of cells overexpressing p16INK4a in said sample. The cells expressing p14ARF need not to be the same cells as those overexpressing p16INK4a although the expression of both marker molecules may occur in the same cells.

Thus, the presence of cells expressing p14ARF gene-products in a sample simultaneously with the presence of cells overexpressing p16INK4a (other cells or the same cells coexpressing both markers) according to the present invention serves to discriminate neoplastic or preneoplastic lesions from metaplasias.

Applicants have amended Claim 1 to recite that in said biological sample, the simultaneous presence of cells overexpressing the one INK4a gene-product and cells expressing

the one different INK4a gene-product is indicative for neoplastic lesions. The amendments have properly addressed the Examiner's species election requirement, without changing the gist of the claimed invention.

In Claim 2, Applicants are electing the one INK4a gene-product being p16^{INK4a}, and the one different INK4a gene product being p14ARF. The above two gene products must be different.

Applicants are electing the enzyme label, and will elect the fluorescent compound as next species if the generic labels are found allowable.

Applicants are electing the probe being an antibody directed against an INK4a encoded gene-product. Applicants also elect the respective technique of using such probe being immunocytochemical staining procedure.

Claims 1-4, 6-16 and 21 read upon the elected species.

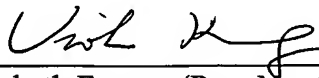
Upon the allowance of a generic claim, Applicant are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.

CONCLUSION

Applicants believe that the application is now in good and proper condition for allowance. Early notification of allowance is earnestly solicited.

Respectfully submitted,

Date: April 18, 2006



Elisabeth Evertsz (Reg. No. 50,304)
Viola T. Kung (Reg. No. 41,131)

HOWREY LLP
2941 Fairview Park Drive, Box 7
Falls Church, VA 22042
Tel. (650) 798-3570
Fax: (650) 798-3600